In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 18-232V

(to be published)

VICTORIA LEMING and KEVIN LEMING, Parents and Natural Guardians of A.L., a Minor, Petitioners, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: February 18, 2022 Special Processing Unit (SPU); Motion for Reconsideration; Diphtheria-tetanus-acellular pertussis (DTaP) Vaccine; Measles-mumps-rubella-varicella (MMRV) Vaccine; Haemophilus influenzae type b (Hib) vaccine; Thrombocytopenic Purpura (ITP); Severity Requirement

Robert Joel Krakow, Law Office of Robert J. Krakow, P.C. New York, NY, for Petitioners.

Julia Marter Collison, U.S. Department of Justice, Washington, DC, for Respondent.

ORDER DENYING MOTION FOR RECONSIDERATION[1]

On February 14, 2018, Victoria and Kevin Leming, on behalf of minor A.L., filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, et seq. (the "Vaccine Program").[2] Petitioners alleged that the measles-mumps-rubella-varicella ("MMRV"), diphtheria-tetanus-acellular pertussis ("DTaP"),

[1] Because this Order contains a reasoned explanation for the action in this case, it will be posted it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Order will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. §§ 300aa-10–34 (2012)) (hereinafter "Vaccine Act" or "the Act"). All subsequent references to sections of the Vaccine Act shall be to the pertinent subparagraph of 42 U.S.C. § 300aa.

and/or Haemophilus influenzae type b ("Hib") vaccines that A.L. received on September 6, 2016, caused her to suffer from immune thrombocytopenic purpura ("ITP"), immune dysfunction, and immunodeficiency. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters (the "SPU").

A short reiteration of the procedural history is warranted, since prior fact determinations bear on the outcome of the present motion. Special Master Dorsey (who was Chief Special Master at the time this matter was initially pending, and hence responsible for SPU cases) previously found that the claim met the Section 11(c)(1)(D)(iii) exception to the Vaccine Act's six-month "severity" requirement, because A.L. had undergone a "surgical intervention" as part of her ITP diagnosis. *Leming v. Sec'y of Health & Hum. Servs.*, No. 18-0232V, 2019 WL 5290838 (Fed. Cl. Spec. Mstr. July 12, 2019), Ruling on Facts (ECF No. 41) (hereinafter "Severity Fact Finding"), *mot. for review granted*, 154 Fed. Cl. 325 (2021).

But Special Master Dorsey's Severity Fact Finding did *not* determine that the six-months sequela requirement under Section 11(c)(1)(D)(i) had been established, and rejected the arguments advanced by Petitioner at that time that relied on the record. Severity Fact Finding, 2019 WL 5290838, at *3-5. The Severity Fact Finding was based on record evidence (much of which was undisputed) that (a) the vaccinations deemed causal of A.L.'s ITP occurred in September 2016, (b) A.L.'s presenting symptoms plus platelet count drops (the *sine qua non* for diagnosing ITP) had resolved within three months, or by December 2016, and (c) no other evidence for any subsequent period evidenced renewed platelet count drops or symptoms return sufficient to establish that the ITP sequelae existed beyond the six-month date. *Id.* at *2. I also note that the Severity Fact Finding was issued in *July 2019* – more than two years after the date of any medical records relevant to A.L.'s case. Hence, it would have been reasonably expected that any additional relevant medical record proof of ITP's recurrence could have been then offered, or that contemporaneous treater views on A.L.'s status might have been asserted at that time.

The Severity Fact Finding's "surgical intervention" determination was subsequently reversed upon Respondent's Motion for Review. *Leming v. Sec'y of Health & Hum. Servs.*, 154 Fed. Cl. 325 (2021), Op. and Order (ECF No. 81) (hereinafter "Remand Order"). On remand, I dismissed this claim – both in adherence to the Court's determination on the surgical intervention issue, but also because (consistent with Special Master Dorsey's earlier findings) Petitioners could not meet the *general* severity requirements set forth in Section 11(c)(1)(D)(i) of the Vaccine Act. ECF No. 96, filed on January 26, 2022 (hereinafter "Decision on Remand"). In so deciding, I considered new arguments made by Petitioners on that point – in particular, that a treating expert had opined that A.L.'s ITP had not subsided, and that A.L. was revealing clinical symptoms

again. Decision on Remand at 9-11. I determined, however, that these arguments were inconsistent with the undisputed medical record, and that A.L. had otherwise never been diagnosed with a chronic/recurring form of ITP. *Id.* at 9-11.

In addition, I delayed issuance of my remand determination beyond the 90-day period provided for in the Vaccine Rules, due to a then-pending Federal Circuit appeal also involving severity in the context of ITP - *Wright v. Sec'y of Health & Hum. Servs.*, 22 F.4th 999 (Fed. Cir. 2022). Decision on Remand at 4 n.5. *Wright,* however, turned not on the surgical intervention exception to six months severity, but on whether non-invasive platelet count testing (performed after primary symptoms and platelet count drops had resolved) was sufficient to establish severity – and the Circuit determined that this did not constitute a "residual effect" of injury under Section 11(c)(1)(D)(i). *Wright,* 22 F.4th at 1005-07. I referenced *Wright* in my Decision on Remand (*see, e.g.*, Decision on Remand at 6, 10), but my determination did not turn on it (although I did observe that *Wright* emphasized that bruising alone, without corroborative evidence (in the form of testing revealing platelet drops) connecting it to ITP, was insufficient to establish severity). Decision on Remand at 10-11.

Petitioners now move for reconsideration of my Decision on Remand. Motion, filed February 10, 2022 (ECF No. 97) ("Reconsideration Mot."). Petitioners specifically argue that the Federal Circuit's opinion in *Wright* represents an intervening change in the controlling case law, articulating a new standard under which severity can be met, and (in Petitioners' view) *is* now met herein. Reconsideration Mot. at 2-3, 29-30. In support of their Motion for Reconsideration, Petitioners have filed updated medical records, an expert report, and multiple items of medical literature. ECF Nos. 98-100.[3]

Standards for Reconsideration

Vaccine Rule 10(e) provides that either party may seek reconsideration of a special master's decision within twenty-one days after the decision's issuance. Special masters have the discretion to grant a motion for reconsideration if to do so would be in the "interest of justice." Vaccine Rule 10(e)(3).

As noted by another special master, "there is a dearth of law interpreting Vaccine Rule 10(e)(3)," save for the conclusion that (as the rule itself makes clear) it is within the special master's discretion to decide what the "interest of justice" is in a given case. *R.K. v. Sec'y of Health & Hum. Servs*., No. 03-632V, 2010 WL 5572074, at *3 (Fed. Cl. Spec.

[3] Respondent has not filed anything in response to the present Motion – and has not in fact had the chance to do so. But because the deadline for seeking review of my Decision on Remand looms in the next several days, and since seeking reconsideration does not operate to stay the 30-day period to seek review, I am ruling on the motion based solely on the Petitioners' briefing order to minimize prejudice to the Petitioners, to the extent they will now choose to proceed with a Motion for Review.

Mstr. Jan. 10, 2011) (granting reconsideration of decision dismissing case for failure to prosecute). Many decisions assume that the standard for reconsideration is congruent with the "manifest injustice" standard utilized under Rule 59(a) of the Rules of the Court of Federal Claims, which has been defined as "clearly apparent or obvious" unfairness. *Amnex, Inc. v. United States*, 52 Fed. Cl. 555, 557 (2002); *see also R.K.*, 2010 WL 5572074, at *3–5 (citations omitted).

I have previously permitted reconsideration when the movant provided new, relevant evidence that would have borne on my initial decision had it been previously available. *See, e.g.*, *Rodriguez-Luna v. Sec'y of Health & Hum. Servs.*, No. 15-496V, 2018 WL 774256, at *2 (Fed. Cl. Spec. Mstr. Jan. 3, 2018) (granting motion for reconsideration of final attorney's fees and costs decision when petitioner submitted previously-unfiled billing records). By contrast, I have denied reconsideration requests where the movant simply disagrees with my initial decision (including how I weighed the evidence), and has otherwise offered no truly "new" evidence. *See, e.g., D'Tiole v. Sec'y of Health & Hum. Servs.*, No. 15-085V, 2016 WL 8136296 (Fed. Cl. Spec. Mstr. Dec. 21, 2016), *mot. for review denied*, 132 Fed. Cl. 421 (2017), *aff'd*, 726 F. App'x 809 (Fed. Cir. 2018); *Kerrigan v. Sec'y of Health & Hum. Servs.*, No. 16-270V, 2016 WL 7575240 (Fed. Cl. Spec. Mstr. Nov. 22, 2016). Intervening precedent can also provide grounds for reconsideration, if it in fact has the potential for altering a matter's prior resolution.

Petitioners Have Not Established Grounds for Reconsideration

As grounds for reconsideration, Petitioners argue that *Wright* has somehow resulted in a "new statutory construction" of the Act's severity requirement (Reconsideration Mot. at 2) – although the thrust of Petitioners' arguments are that this case presents *distinguishable* facts from *Wright,* even though it also involves ITP. *Id.* at 15. Testing performed on A.L. in June 2017 (and hence evidence that existed at the time of the original 2019 Severity Fact Finding), Petitioners maintain, revealed "platelet abnormality and immune dysregulation," based on then-elevated B cell levels plus proof of "giant platelets." *Id.* at 9-10. (Petitioners obtain this information from records previously filed, and argued over). Thus, this possibility of immune dysfunction suggests a post-ITP sequelae, or that "the residual ITP process had continued." *Id.* at 22. Moreover, Petitioners offer a new expert report opining that that "the presence of large platelets . . . in June 2017 explains why [A.L.] continued to experience bruising at that time, even considering that the acute phase of her ITP had passed." Report of Mark Levin, M.D., dated February 8, 2022, filed as Ex. 24 (ECF No. 98-1 at 8). This too, Petitioners reason, supports a finding of a post-vaccine injury "residual effect."

While the Petitioners have offered a lengthy, 30-page brief, new expert report, and twelve additional items of medical/scientific literature to support their reconsideration

argument, the foregoing amounts to far less than meets the eye – and does not meet the standards for reconsideration, for several reasons.

First, Petitioners rely on record evidence already considered in this case multiple times – and which, when weighed by *two* special masters, was deemed insufficient to establish severity under Section 11(c)(1)(D)(i). They thus reference no new medical findings or evidence. The June 2017 testing findings were expressly considered in the Severity Fact Finding – but, when weighed against other evidence (including the fact that "A.L.'s treating immunologist did not attribute any June 29, 2017 bruising to A.L.'s previous ITP diagnosis") did not find severity met. Severity Fact Finding, at *4-5. All Petitioners do now is approach the problem from a new angle, emphasizing for the first time "the giant platelets noted on smear review" in conjunction with Petitioner's bruising and B cell findings from this timeframe – findings that Special Master Dorsey also noted ultimately returned "good" results. *Id.* (citing Ex. 10 at 8-9; Ex. 12 at 2).[4] And there otherwise is no evidence offered establishing immune dysregulation after the ITP had resolved, such that it could constitute some other form of ITP sequelae.

The "new" medical record filed in conjunction with the Motion for Reconsideration is only recent in terms of its date of creation. Petitioners have filed records from Texas Children's Hospital detailing recent lab work from October 2021, and prior lab work from 2017, as well as an encounter with A.L.'s pediatric immunologist, Lisa Forbes, MD, on November 11, 2021, at which time Dr. Forbes reviewed A.L.'s current and prior labs. *See generally* Ex. 38 (ECF No. 99). But in this record, Dr. Forbes indicates that "[l]ab interpretation from 2017: [h]er transitional B cell percentage as well there [sic] CD19+CD38loCD21lo B cells (autoimmune) has decreased, and her B cells are normal for age." *Id.* at 28. Indeed, Dr. Forbes' current assessment of A.L. notes she "is a 6 y[ear] o[ld] with a history of ITP and *normalized since her first visit with me in 2017*." *Id.* at 29 (emphasis added). She adds that A.L. "has not had any ITP flares since we first met her" and that mom was being seen to "revis[it] vaccination and decide how to move forward." A vaccination scheduled was established. *Id.* at 26, 29.[5] The October 2021 lab results were not interpreted by Dr. Forbes as suggesting A.L. was at risk for ITP or immune dysfunction. Further, A.L.'s platelet value tested within the normal range.[6] Ex. 38 at 3.

[4] I also addressed this point in the Decision on Remand. Decision on Remand at 10 n11.

[5] Petitioners again assert in their Motion that A.L.'s inability to receive routine childhood vaccinations constitutes a residual effect or complication of her injury. Reconsideration Mot.at 24-29. I addressed this argument in the Decision on Remand. I further note that the medical records do not support the argument that Dr. Forbes recommended that Petitioner delay vaccinations. Rather, the records only demonstrate that Dr. Forbes recently met with A.L.'s mother to discuss her "risks for vaccine reaction" and develop a catch-up vaccination schedule. Ex. 38 at 26, 29.

[6] Petitioners provided medical records obtained through the patient portal as updated records from the provider had not yet been received. Reconsideration Mot. At 5 n.2.

There is thus no new evidence generated since the time of *either* my Decision on Remand *or* the Severity Fact Finding issued *two years before* that justifies reconsideration.[7]

At most, Petitioners attempt to highlight a *different* aspect of the record (the giant platelets and/or B cell levels) that they did not previously reference. But putting aside that they neglected to advance this argument at an earlier date, there are no legitimate changes in the scientific understanding of ITP that Petitioners' Motion identifies that would render this aspect of the record more significant today than it was in 2019. As *Wright* notes, ITP is not present if a serum platelet count is normal (exceeding 150,000/mm), and the Table definition for post-MMR ITP (which closely tracks the medical scientific views of what constitutes ITP) requires showing platelet counts below 50,000/mm. *Wright,* 22 F.4th at 1002-03 (citations omitted). Thus, bruising alone (and whatever might cause that) is not enough to prove the injury.

None of the literature filed by Petitioners changes this understanding -- even if some items were published after the original Severity Fact Finding. Rather, they merely discuss the role that B cells or platelet size play in ITP's pathogenesis (and what in turn that says about treatment of ITP *while* it is occurring) – *not* that B cells or giant platelets establish ITP's lingering presence, in the absence of evidence of platelet count drops. *See, e.g.*, T. Yu et al., *Abnormalities of Bone Marrow B Cells and Plasma Cells in Primary Immune Thrombocytopenia,* 5 Blood Advances 4087, 4099 (2021), filed as Ex. 34 (ECF No. 98-11) ("[t]he abnormalities of BM B cells and their chemotactic environments might provide new therapeutic targets for the management of ITP"); S. Handtke & T. Thiele, *Large and Small Platelets – (When) Do They Differ?*, 18 J. Thromb. Haemost. 1256, 1262 (2020), filed as Ex. 31 (ECF No. 98-8) (large platelets are seen in ITP cases). Thus, this new literature does not alter the earlier determination (in the Severity Fact Finding and then the Decision on Remand) that A.L.'s ITP did not exist or have sequelae sufficient to meet the Act's severity requirement.

I also note that the *Wright* decision is no basis for reconsideration either. *Wright* was not only decided *before* issuance of my Decision on Remand, but is *cited therein.* It is not binding precedent that I could not have taken into account in rendering my Decision – to the contrary, *I did consider it*. And while I did not then invite Petitioners to offer their

[7] In addition, these are arguments that could have been advanced by Petitioners at the time of the Severity Fact Finding (and also could have been raised with the Court of Federal Claims at the time the Motion for Review was addressed – as alternative bases for supporting severity regardless of the correctness of the Severity Fact Finding's surgical intervention determination or pursuant to my Order to Show Cause issued prior to my Decision on Remand). While it is true that from a strictly legal standpoint (as I observed in my Decision on Remand) Petitioners have not literally "waived" such arguments, I reasonably take into account Petitioners' failure to offer them at the appropriate time in denying the present motion. Reconsideration is not an occasion for counsel to craft new arguments to replace prior ones that did not succeed – especially where, as here, claimants have had an ample opportunity to prove their claim.

parsing of *Wright,* I now have the benefit of their reading of it, but find it wholly unpersuasive. The *Wright* panel considered the definition of "residual effects" in the context of the alleged condition, ITP, but deemed platelet level testing conducted after the affected child's levels had reverted to normal to not constitute a "residual effect" of the prior ITP. Not only were the tests themselves not "lingering signs and symptoms of the original vaccine injury," but the tests *revealed* no further "signs and symptoms" of ITP – and the tests otherwise caused no detriment to the injured child's health that could reflect a secondary sequela of the original injury. *Wright,* 22 F.4th at 1006. *Wright* says nothing about the kind of *non-test-related* symptoms or evidence that might satisfy severity, and thus it does not facially aid Petitioners by altering how severity should be analyzed.

At bottom, this is a case in which the alleged injury cannot be shown to have resulted in the six-months of sequelae required for *any* Vaccine Act claim. The core element of A.L.'s ITP injury – platelet count drops – resolved well prior to the expiration of that timeframe. This means the claim is not sustainable, in the absence of other sequelae – and Petitioners have not mined gold, so to speak, from a record that was already bare on this front. Petitioners may be desirous of keeping the claim alive by continuing to refine their contentions, making use of the time it is taking to fully resolve the case – but I do not find that their arguments are grounded in the case's facts or the law, all of which they have had ample opportunity to argue. At this point, if Petitioners believe the Decision on Remand is in error, they are best served by seeking its review.

I therefore **DENY** the Motion for Reconsideration.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master